General

Guideline Title

American Academy of Orthopaedic Surgeons clinical practice guideline on the treatment of osteoarthritis of the knee, 2nd edition.

Bibliographic Source(s)

American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on treatment of osteoarthritis of the knee. 2nd ed. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2013 May 18. various p. [137 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Orthopaedic Surgeons (AAOS). Treatment of osteoarthritis of the knee (non-arthroplasty). Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2008 Dec 6. 263 p.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines : A U.S. Food and Drug Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Definitions of the strength of recommendations (Strong, Moderate, Limited, Inconclusive, and Consensus) are provided at the end of the "Major Recommendations" field.

Note from the American Academy of Orthopaedic Surgeons (AAOS): This summary of the AAOS clinical practice guideline "Treatment of Osteoarthritis of the Knee" contains a list of the evidence-based treatment recommendations and includes only less invasive alternatives to knee replacement. Discussion of how and why each recommendation was developed and the evidence report are contained in the full guideline from the AAOS Web site. Readers are urged to consult the full guideline for the comprehensive evaluation of the available scientific studies (see the "Availability of the Companion Documents" field). The recommendations were established using methods of evidence-based medicine that rigorously control for bias, enhance transparency, and promote reproducibility.

Conservative Treatments

Recommendation 1

The work group recommends that patients with symptomatic osteoarthritis of the knee participate in self-management programs, strengthening, low-impact aerobic exercises, and neuromuscular education; and engage in physical activity consistent with national guidelines.

Strength of Recommendation: Strong

Recommendation 2

The work group suggests weight loss for patients with symptomatic osteoarthritis of the knee and a body mass index (BMI) ≥25.

Strength of Recommendation: Moderate

Recommendation 3A

The work group cannot recommend using acupuncture in patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Strong

Recommendation 3B

The work group is unable to recommend for or against the use of physical agents (including electrotherapeutic modalities) in patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Inconclusive

Recommendation 3C

The work group is unable to recommend for or against manual therapy in patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Inconclusive

Recommendation 4

The work group is unable to recommend for or against the use of a valgus directing force brace (medial compartment unloader) for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Inconclusive

Recommendation 5

The work group cannot suggest that lateral wedge insoles be used for patients with symptomatic medial compartment osteoarthritis of the knee.

Strength of Recommendation: Moderate

Recommendation 6

The work group cannot recommend using glucosamine and chondroitin for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Strong

Pharmacologic Treatments

Recommendation 7A

The work group recommends nonsteroidal anti-inflammatory drugs (NSAIDs; oral or topical) or Tramadol for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Strong

Recommendation 7B

The work group is unable to recommend for or against the use of acetaminophen, opioids, or pain patches for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Inconclusive

Procedural Treatments

Recommendation 8

The work group is unable to recommend for or against the use of intraarticular (IA) corticosteroids for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Inconclusive

Recommendation 9

The work group cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Strong

Recommendation 10

The work group is unable to recommend for or against growth factor injections and/or platelet rich plasma for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Inconclusive

Recommendation 11

The work group cannot *suggest* that the practitioner use needle lavage for patients with symptomatic osteoarthritis of the knee.

Strength of Recommendation: Moderate

Surgical Treatments

Recommendation 12

The work group cannot recommend performing arthroscopy with lavage and/or debridement in patients with a primary diagnosis of symptomatic osteoarthritis of the knee.

Strength of Recommendation: Strong

Recommendation 13

The work group is unable to recommend for or against arthroscopic partial meniscectomy in patients with osteoarthritis of the knee with a torn meniscus.

Strength of Recommendation: Inconclusive

Recommendation 14

The practitioner might perform a valgus producing proximal tibial osteotomy in patients with symptomatic medial compartment osteoarthritis of the knee.

Strength of Recommendation: Limited

Recommendation 15

In the absence of reliable evidence, it is the opinion of the work group not to use the free-floating (un-fixed) interpositional device in patients with symptomatic medial compartment osteoarthritis of the knee.

Strength of Recommendation: Consensus

Definitions:

Recommendation Strengths, Descriptions, and Clinical Implications

Evidence Rating	Description of Evidence Strength	Implication for Practice
Strong	Evidence is based on two or more "High" strength studies with consistent findings in support of recommending for or against the intervention. A Strong (positive) recommendation means that the benefits of the recommended approach clearly exceed the potential harm, and/or that the strength of the supporting evidence is high. A Strong (negative) recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.	Practitioners should follow a Strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate	Evidence from two or more "Moderate" strength studies with consistent results, or evidence from a single "High" quality study recommending for or against the intervention. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong.	Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.
Limited	Evidence from two or more "Low" strength studies with consistent results, or evidence from a single Moderate quality study recommending for or against the intervention or diagnostic. A Limited recommendation means the strength of the supporting evidence is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.	Practitioners should exercise clinical judgment when following a recommendation classified as Limited, and should be alert to emerging evidence that might negate the current findings. Patient preference should have a substantial influencing role.
Inconclusive	Evidence from a single low strength study or otherwise conflicting findings that do not allow a recommendation to be made for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.	Practitioners should feel little constraint in following a recommendation labeled as Inconclusive, exercise clinical judgment, and be alert for emerging evidence that clarifies or helps to determine the balance between benefits and potential harm. Patient preference should have a substantial influencing role.
Consensus	The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A Consensus recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria in the systematic review.	Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may give it preference over alternatives. Patient preference should have a substantial influencing role.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Osteoarthritis of the knee

Note: This guideline provides only treatment recommendations that are less invasive alternatives to knee replacement.

Guideline Category

Management

Rehabilitation

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Orthopedic Surgery

Physical Medicine and Rehabilitation

Rheumatology

Intended Users

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Occupational Therapists

Physical Therapists

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To evaluate the current best evidence associated with treatment of osteoarthritis of the knee

- To guide qualified physicians and clinicians in making treatment decisions that improve the quality and efficacy of care
- To assist treatment providers not only in making clinical decisions with their patients, but also in describing to patients and their loved ones why a selected intervention represents the best available course of treatment

Target Population

Adults (ages 19 years and older) who have been diagnosed by a physician with osteoarthritis of the knee and are undergoing treatment

Note: This guideline does not address patients diagnosed with rheumatoid arthritis, osteoarthritis of other joints, or other inflammatory arthropathies.

Interventions and Practices Considered

1. Conservative treatments
    - Self-management programs
    - Strengthening exercises
    - Low-impact aerobic exercises
    - Neuromuscular education
    - Physical activity consistent with national guidelines
    - Weight loss for those with a body mass index ≥25
2. Pharmacological treatments
    - Nonsteroidal anti-inflammatory drugs (NSAIDs; oral or topical)
    - Tramadol
3. Surgical treatment: valgus producing proximal tibial osteotomy

Note: No recommendation for or against use could be made for the following interventions: use of physical agents (including electrotherapeutic modalities); manual therapy; use of a valgus directing force brace (medial compartment unloader); acetaminophen, opioids, or pain patches; intraarticular corticosteroids; growth factor injections and/or platelet rich plasma; arthroscopic partial meniscectomy.

Note: The following interventions were considered but not recommended: acupuncture, lateral wedge insoles, glucosamine and chondroitin, hyaluronic acid, needle lavage, arthroscopy with lavage and/or debridement, free-floating (un-fixed) interpositional device.

Major Outcomes Considered

- Pain relief
- Functional status
- Range of motion

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Study Selection Criteria

The American Academy of Orthopaedic Surgeons (AAOS) developed *a priori* article inclusion criteria that are the group's "rules of evidence" for the systematic review and meta-analyses. Articles that did not have the selection characteristics were not eligible to be included as evidence for purposes of this guideline.

To be included an article had to meet the following selection criteria:

- Study was of osteoarthritis of the knee.
- Study reported on 80% of the patient population of interest.
- Article provided full report of a clinical study.
- Retrospective non-comparative case series, medical records review, meeting abstracts, historical articles, editorials, letters, and commentaries were *excluded*.
- Case series studies that gave patients the treatment of interest AND another treatment were *excluded*.
- Case series studies that had non-consecutive enrollment of patients were *excluded*.
- Controlled trials in which patients were not stochastically assigned to groups AND in which there was heterogeneity in patient characteristics or outcomes at baseline AND where the authors did not statistically adjust for these differences when analyzing the results were *excluded*.
- All studies of "Very Limited" evidence strength were *excluded*.
- Composite measures or outcomes were *excluded* even if they were patient-oriented.
- Case series studies were *excluded* if no baseline values were reported.
- Study was published in a peer-reviewed journal.
- Study had a sample of 30 or more patients per treatment group.
- Study was of humans.
- Study was published in English.
- Study was published during or after 1966.
- Study results were presented quantitatively.
- Study treatment follow up period was at least 4 weeks.
- At least 80% of the enrolled study population were 19 years of age or older.
- For any included study that used "paper-and-pencil" outcome measures (e.g., Short-Form 36 Health Survey [SF-36]), only those that were validated were included [unless the outcome was identified *a priori* by the work group in the critical outcomes Delphi round]
- "Paper and pencil" outcomes reported by a single group of investigators (i.e., a single study) were *excluded*.
- Study was in vitro.
- Study was not performed on cadavers.

AAOS did not incorporate systematic reviews, meta-analyses, or other guidelines not specified by the guideline workgroup to avoid including studies that did not meet the AAOS's own criteria for selection. Rather, the AAOS research analyst recalled individual studies if the abstracts suggested that they might constitute evidence for one of the recommendations and also searched the bibliographies of published systematic reviews for any additional studies that potentially supplemented AAOS evaluation.

See the original guideline document for discussion on the outcomes considered and the effects of treatments in terms of the minimal clinically important improvement (MCII).

Literature Searches

The AAOS research analyst began the systematic review with a comprehensive search of the literature. Articles considered were published prior to May 2012 in four electronic databases; PubMed, EMBASE, CINAHL, and The Cochrane Central Register of Controlled Trials. The medical librarian conducted the search using key terms determined from the work group's preliminary recommendations.

The work group supplemented the electronic search with a manual search of the bibliographies of all retrieved publications, recent systematic reviews, and other review articles for potentially relevant citations. Recalled articles were evaluated for possible inclusion based on the study selection criteria and were summarized for the work group who assisted with reconciling possible errors and omissions.

The study attrition diagram in Appendix IV of the original guideline document provides a detailed description of the numbers of identified abstracts recalled and selected studies that were evaluated in the systematic review of this guideline. The search strategies used to identify the abstracts are contained in Appendix V of the original guideline document.

Number of Source Documents

A total of 218 articles were considered for recommendations.

Methods Used to Assess the Quality and Strength of the Evidence

Rating Scheme for the Strength of the Evidence

Appraising Evidence Quality and Applicability

Quality

The American Academy of Orthopaedic Surgeons (AAOS) determines quality based on *a priori* research questions and uses an automated numerical scoring process to arrive at final ratings. Extensive measures are taken to determine quality ratings so that they are free of bias.

AAOS evaluates the quality of evidence separately for each outcome reported in every study using research design domains suggested by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) work group members and others. The GRADE evidence appraisal system is used in the Cochrane Collaboration and has been developed for studies evaluating matched control groups. AAOS incorporates a coding scheme adaptable to all research designs that involves incremental increases for:

- Prospective design (evaluation of *a priori* hypotheses)
- Adequate statistical power
- Stochastic random assignment of patients to comparison groups
- Sufficient blinding to mitigate against a placebo effect
- Comparability of the patient groups at the beginning of the study
- Delivery of treatment in a manner where observed differences between the comparison groups could reasonably be attributed to the treatment
- Validated outcome measures
- Absence of investigator bias

Each of the above quality domains is rated for possible flaws based on up to four indicator questions that define them. See Appendix VI in the original guideline document for a discussion of the American Academy of Orthopaedic Surgeons (AAOS) appraisal system. Domains are considered "flawed" if one indicator is coded "No" or at least two defining questions are "Unclear." The Statistical Power domain is considered flawed if sample size is too small to detect at least a small effect size of 0.2.

If there are flawed domains then the evidence quality is downgraded according to the reductions shown in the table below. As an example, the evidence reported in a randomized controlled trial (RCT) for any given outcome is rated as "High" quality if zero or one domain is flawed. If two or three domains are flawed, the rating is reduced to "Moderate." If four or five domains are flawed, the quality of evidence is downgraded to "Low." The quality of evidence is reduced to "Very Low" if six or more domains are flawed. As indicated above, very low quality evidence is not included in this AAOS guideline.

Relationship between Quality and Domain Scores for Interventions

Number of Flawed Domains	Strength of Evidence
0-1	High
2-3	Moderate
4-5	Low
>5	Very Low

The following flaws are so detrimental that AAOS appraises the evidence as "Very Low" quality regardless of the computed domain scores.

- Non-consecutive enrollment of patients in a case series
- Case series involving the administration of multiple treatments
- Heterogeneity in outcome measurement
- Low statistical power

Quality is one of two dimensions that determines the strength of the final recommendations.

Applicability

AAOS rates the applicability (also referred to as "generalizability" or "external validity") of each outcome reported in the studies. As with quality, applicability ratings are based on pre-established indicators that are coded and scored algorithmically. Applicability is rated as "High," "Moderate," or "Low," based on the number of domains that are flawed. A study is rated "High" if none of the domains are flawed, "Low" if all of the domains are flawed, and "Moderate" in all other cases.

Relationship between Applicability and Domain Scores for Interventions

Number of Flawed Domains	Applicability
0	High
1, 2, 3	Moderate
4	Low

AAOS's applicability appraisal system is derived from the PRECIS instrument originally intended for randomized controlled trials but also appropriate for other types of research design. It is comprised of 10 questions that are divided into four domains. The defining characteristics and domains are presented in Table 3 of the original guideline document.

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Best Evidence Synthesis

When determining the best available evidence, the American Academy of Orthopaedic Surgeons (AAOS) first includes the highest-strength studies available for the outcomes examined. If there are two or more high-strength studies, the recommendation grade is strong. In this case, moderate- and low-strength evidence do not influence the grade of the recommendation. If there is one high- or at least two moderate-strength studies, the recommendation grade is moderate. If there is one moderate- or at least two low-strength studies, the recommendation grade is limited. Inconclusive recommendation grades are assigned when there is one low-strength study, no evidence, or contradictory findings. In this case, the rules for using expert opinion are not applicable so consensus recommendations are not appropriate. Consensus based recommendations are established only when the strength of the evidence would otherwise be inconclusive and the rules for consensus recommendations apply. See the section on Consensus Recommendations in the original guideline document (page 21).

Statistical Methods

Network Meta-analysis

During evidence appraisal of this guideline Bayesian network meta-analyses (also known as mixed treatment comparisons analysis) of randomized controlled trials were performed to ascertain the comparative effectiveness of analgesic treatments not directly compared in the literature, as explained below. For all interventions connected in one network by pairwise relationships, if there is no direct evidence about two analgesics but they are each compared to the same reference treatment then their relative effectiveness can be estimated based on their computable effects with the common comparator. Both direct and indirect comparisons contribute to the totality of evidence for selecting the best choices of treatment. The mixed treatment comparisons analysis follows methodology described by Lu and Ades using Winbugs version 1.4.

Network meta-analysis assumes that randomization within the individual trials is maintained. Additionally, it is appropriate when interactions and covariates that affect trial AB have similar effects on trial AC, and the same indirect effect BC could be obtained as if it had been evaluated as a true direct effect (i.e., third arm of the randomized controlled trial [RCT]). Breaking randomization and permitting effect modifying heterogeneity leads to biased estimates of the indirect comparisons. Consistency, the second important assumption, helps to produce interpretable results along with the similarity requisite. Similarity is required of the treatment effects among studies; consistency addresses the potential for significant variability between the direct and indirect comparisons.

Network meta-analysis requires statistical consistency between the direct and indirect pairwise effects. The work group uses the "back calculation" method as described by Dias et al. summarized as follows. Indirect effect BC is calculated as the difference between direct effects AB and AC and evaluated against the direct effect estimation for BC. The z-statistic for the difference between the direct and indirect effects of BC is compared to a standard normal distribution to test the null hypothesis evaluating consistency. If statistical significance is found, then the model is interpreted as having questionable reliability and is excluded from the data analysis. The results of the tests of statistical consistency between the direct and indirect comparisons of the pairs of analgesics examined in this guideline indicated that the consistency assumption was met; the output summary can be found in Appendix XIII of the original guideline document.

Network meta-analysis is based on multiple pairwise comparisons across at least three RCTs that connect at least three interventions where there is at least one closed loop (i.e., common comparator; direct comparison). It is an extension of traditional meta-analysis that incorporates a process where the outcome of a given comparison can affect the next outcome requiring the convergence of Markov chains that is based on this type of sampling. A total of k-1 parameters are estimated that allow for multiple pairwise comparisons across a range of k distributions. The results are assessed by examination of trace plots that graphically display the values a parameter took during the runtime of the chain. In general, for each network model the work group performed 100,000 iterations of which the first 50,000 were discarded as "burn in" pre-convergence iterations. Occasionally models required 100,000 burn-in pre-convergence iterations, which resulted in a total of 150,000 iterations.

Placebo Data Regression Analysis

Inclusion Criteria

As part of the studies included in the full guideline, articles that met inclusion criteria for a supplementary osteoarthritis of the knee placebo project were also recalled. Selection criteria included:

- Studies written in English
- Placebo-controlled randomized controlled trial study design evaluating treatment for knee osteoarthritis
- ≥80% of participants have osteoarthritis of the knee (or the results for those with knee osteoarthritis reported separately)
- Study reported patient-oriented outcomes (i.e. pain, function, global assessment)
- Study reported sufficient data from the placebo group to perform statistical analysis: baseline and follow-up measures or change from baseline measures, including measures of dispersion (95% confidence interval, standard deviation, or standard error)
- Withdrawal rate of placebo group <20% (measured at each treatment follow up duration)

Because of differences in inclusion criteria between the placebo data project and the full guideline, some articles were included only in the placebo study while others were a part of both. As an example, sample size ≥30 was not a selection criterion for the regression analysis but it was for the full guideline.

AAOS searched placebo controlled trials relevant to all the recommendations for the following outcomes: Western Ontario and McMaster Universities Index (WOMAC) pain, stiffness, function, and total subscales, Visual Analogue Scale (VAS) pain, Short Form (SF)-36 role-physical and mental subscales, and the Lequesne Index. The only data available examined the treatment efficacy of osteotomy using the VAS; so only placebo controlled trials that measured change in VAS pain following osteotomy were incorporated.

Statistical Analysis

Data from 48 articles were extracted to predict differences between baseline and treatment scores in the experimental and placebo groups of two case series designed studies. Prais-Winsten regression analysis was conducted using STATA's XTP CSE command used specifically with panel data affected by heteroskedasticity and autocorrelation. Since each observation represented study-level averages of Visual Analog Scale (VAS) pain scores, the regression was weighted by size of the study samples.

The initial regression model predicted change in VAS pain using pretreatment score, age, percent female, follow up duration in weeks, multicenter study (0 = yes, 1 = no), and allowance for concomitant treatment (0 = no, 1 = yes) as independent variables. Blinding was not used as a predictor variable because patients were masked to the treatment assignments in all but one of the studies.

Refer to the "Methods" section in the original guideline document for more information, including a section on Minimal Important Difference (MID) Units.

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

The work group met for the introductory meeting on April 25, 2010 to establish preliminary recommendations and search terms for the guideline's systematic review. A two-day final meeting convened on August 25-26, 2012 where members voted on final recommendations following a review of the evidence, wrote the rationales, and approved the methodological contents of the guideline.

Formulating the Preliminary Recommendations

Based on their expert views of what works best, with whom, and under what circumstances, the work group's preliminary recommendations establishes the focus of the systematic review and determines the contents for the final conclusions. All preliminary recommendations are worded in the affirmative direction.

Modifications to the preliminary recommendations are not permitted between the introductory and final work group meetings. Only editing in accordance with the best available evidence and AAOS rules for wording recommendations based on evidence strengths are adopted. Modifications that require new literature searches or are not evidence-based are also not permitted.

Full Disclosure Information

The work group's preliminary recommendations are represented in this guideline and the empirical studies that the analysts examined are cited. The American Academy of Orthopaedic Surgeons (AAOS) has always striven for total transparency in the guideline development process.

Defining the Strength of the Recommendations

Judging the strength of evidence is only one step in the process of arriving at the final grade of a guideline recommendation. The overall strength is also based on clinical appropriateness, volume of the evidence, benefit versus potential harm to the patient's well-being, magnitude of treatment effects, and available data on critical outcomes.

It is highly unlikely that future evidence will overturn a recommendation supported by numerous high strength randomized controlled trials that show a large treatment effect. There is a greater likelihood for future evidence to contradict recommendations that are based on a small number of case series. Since RCTs tend to have higher scientific merit, they are usually associated with higher evidence strengths than case series studies.

When determining strength, AAOS staff first assigns a preliminary grade for each recommendation that reflects the quality and applicability ratings as well as volume of the evidence. Work group members then modify the preliminary recommendation strengths using the "Form for Assigning Strength of Recommendation (Interventions)" shown in Appendix VI of the original guideline document. See the "Rating Scheme for the Strength of the Evidence" field for the possible grades, definitions, and implications that can be assigned to recommendations.

Consensus Recommendations

Consensus recommendations are based on expert opinion. While they are prudent in certain instances, their liberal use can cause a source of bias. When the AAOS uses consensus-based recommendations, they follow the procedures described by the U.S. Preventive Services Task Force (USPSTF). In their view, there are only two circumstances that warrant their use. The first is in the case of procedures that have virtually no associated harm, are of relatively low cost, and reflect routine clinical care. The second pertains to medical interventions that potentially prevent loss of life or limb.

In making consensus-based recommendations, work group members consider:

- Preventable burden of disease
- Applications in current practice
- Potential harm that could result from providing a medical service
- Relative difference in costs of a recommended service over alternatives

The AAOS employs additional rules to manage the potential bias that may influence consensus recommendations. First, the rationale cannot contain references to studies that are not a part of the systematic review. Excluded articles are not viewed as evidence. Second, the final recommendation must use the language shown in Table 5 of the original guideline document that eliminates stating "we recommend," "we suggest," or "the practitioner might" to avoid confusion with the evidence-based recommendations. Third, the rationale must address any apparent discrepancies in logic with other recommendations. For example, if a guideline does not endorse an intervention in some instances but the work group has nevertheless issued a consensus-based recommendation, the rationale must explain the reason for the discrepancy in decisions.

When a recommendation is equivocal (i.e., when the recommendation reads "we are unable to recommend for or against"), the explanation why cannot contain an implied recommendation. For example, in the case of a new device, drug, or procedure, the work group may not incorporate

such statements as, "Although treatment X *appears to be promising*, there is currently insufficient evidence to recommend for or against its use." The italicized phrase implies effectiveness in treatment X when "not being able to recommend for or against" implies that effectiveness remains undetermined.

Voting on the Recommendations

The recommendations and their strengths are voted on using the nominal group technique. AAOS presents the details in Appendix VIII of the original guideline document. Voting is conducted by secret ballot; work group members are blinded to the responses of the other members. If there is significant disagreement, negotiation takes place and is followed by up to an additional three rounds of voting. If the disagreements cannot be resolved, the applicable recommendation is not adopted. Lack of agreement is a reason some grades might be labeled "Inconclusive."

Formal vote by work group members was used to approve all of the recommendations. Only the work group chair is required to approve the rationales with the editing support of staff unless the evidence grade is consensus. However, the rationales for this guideline were approved by the entire work group. All components of consensus recommendations require formal vote.

Rating Scheme for the Strength of the Recommendations

Grade of Recommendation

The recommendation grades are based on the strengths of evidence and express the confidence one can have in the final recommendations. Grades reflect how likely it is current findings will be replicated in future studies. They are assigned as "Strong," "Moderate," or "Limited."

The American Academy of Orthopaedic Surgeons (AAOS) bases evidence grades on the quality and applicability ratings, whether or not the studies report critical outcomes, and potential harm to patients. More specifically, they begin by setting the strength as equal to the quality of available evidence. High quality evidence is preliminarily rated as "Strong," moderate quality as "Moderate," and low quality as "Limited." The ratings are downgraded if the evidence is: 1) of "Low" applicability; 2) inconsistent (comprised of studies with discrepant findings or a high degree of heterogeneity in the meta- or network meta-analyses); 3) based on only one study; or, 4) lacking "critical" outcomes. Preliminary recommendation grades are adjusted upward if the evidence is of "High" applicability or if the intervention is associated with decreased likelihood of catastrophic harm (i.e., possible loss of life or limb). In the present guideline, reducing potential harm is the reason that the evidence strength of one recommendation was raised.

Wording of the Final Recommendations

To prevent bias in the way recommendations are worded, the AAOS uses specific predetermined language stems that are governed by the evidence strengths. The format of guideline language is shown in the Table below.

AAOS Guideline Language

Guideline Language Stem	**Grade**
The work group *recommends*	Strong
The work group *suggests*	Moderate
The practitioner *might*	Limited
The work group is *unable to recommend for or against*	Inconclusive
In the absence of reliable evidence, the *opinion* of this work group is*	Consensus*

*Consensus recommendations are made only if specific criteria are met. See the "Consensus Recommendations" section in the "Description of the Methods Used to Formulate Recommendations" field.

Recommendation Strengths, Descriptions, and Clinical Implications

Evidence Rating	**Description of Evidence Strength**	**Implication for Practice**
Strong	Evidence is based on two or more "High" strength studies with consistent findings in support of recommending for or against the intervention.	Practitioners should follow a Strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Evidence Rating	Description of Evidence Strength	Implication for Practice
	A Strong (positive) recommendation means that the benefits of the recommended approach clearly exceed the potential harm, and/or that the strength of the supporting evidence is high. A Strong (negative) recommendation means that the quality of the supporting evidence is high. A harms analysis on this recommendation was not performed.	
Moderate	Evidence from two or more "Moderate" strength studies with consistent results, or evidence from a single "High" quality study recommending for or against the intervention. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong.	Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.
Limited	Evidence from two or more "Low" strength studies with consistent results, or evidence from a single Moderate quality study recommending for or against the intervention or diagnostic. A Limited recommendation means the strength of the supporting evidence is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.	Practitioners should exercise clinical judgment when following a recommendation classified as Limited, and should be alert to emerging evidence that might negate the current findings. Patient preference should have a substantial influencing role.
Inconclusive	Evidence from a single low strength study or otherwise conflicting findings that do not allow a recommendation to be made for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.	Practitioners should feel little constraint in following a recommendation labeled as Inconclusive, exercise clinical judgment, and be alert for emerging evidence that clarifies or helps to determine the balance between benefits and potential harm. Patient preference should have a substantial influencing role.
Consensus	The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A Consensus recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria in the systematic review.	Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may give it preference over alternatives. Patient preference should have a substantial influencing role.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

Following the final meeting, the guideline draft undergoes peer review for additional input from external content experts. Written comments are provided on the structured review form (see Appendix IX of the original guideline document). All peer reviewers are required to disclose their conflicts of interest.

To guide who participates, the work group identifies specialty societies at the introductory meeting. *Organizations*, not *individuals*, are specified.

The specialty societies are solicited for nominations of individual peer reviewers approximately six weeks before the final meeting. The peer review period is announced as it approaches and others interested are able to volunteer to review the draft. The chair of the American Academy of Orthopaedic Surgeons (AAOS) committee on Evidence Based Quality and Value reviews the draft of the guideline prior to dissemination.

Some specialty societies (both orthopaedic and non-orthopaedic) ask their evidence-based practice (EBP) committee to provide review of the guideline. The organization is responsible for coordinating the distribution of AAOS materials and consolidating their comments onto one form. The chair of the external EBP committees provides disclosure of their conflicts of interest (COI) and manages the potential conflicts of their members.

The AAOS asks for comments to be assembled into a single response form by the specialty society and for the individual submitting the review to provide disclosure of potentially conflicting interests. The peer review stage gives external stakeholders an opportunity to provide evidence-based direction for modifications that they believe have been overlooked. Since the draft is subject to revisions until its approval by the AAOS Board of Directors as the final step in the guideline development process, confidentiality of all working drafts is essential.

The clinical practice guidelines manager drafts the initial responses to comments that address methodology. These responses are then reviewed by the work group chair and vice-chair, who respond to questions concerning clinical practice and techniques. The director of the Department of Research and Scientific Affairs provides input as well. All comments received and the initial drafts of the responses are also reviewed by all members of the work group. All changes to a recommendation as a result of peer review are based on the evidence and undergoes majority vote by the work group members via teleconference. Final revisions are summarized in a detailed report that is made part of the guideline document throughout the remainder of the review and approval processes.

The AAOS believes in the importance of demonstrating responsiveness to input received during the peer review process and welcomes the critiques of external specialty societies. Following final approval of the guideline, all individual responses are posted on the AAOS Web site with a point-by-point reply to each non-editorial comment. Reviewers who wish to remain anonymous notify the AAOS to have their names de-identified; their comments, AAOS responses, and their COI disclosures are still posted.

Review of the *Treatment of Osteoarthritis of the Knee* guideline was requested of 19 organizations and 18 external content experts were nominated to represent them. Sixteen individuals returned comments on the structured review form (see Appendix X of the original guideline document).

Public Comment

After modifying the draft in response to peer reviewers' input, the guideline is circulated for a 30-day public comment period. Public commentators consist of members of the AAOS Board of Directors (BOD), Council on Research and Quality (CORQ), Board of Councilors (BOC), and Board of Specialty Societies (BOS). The guideline draft is customarily sent to the AAOS BOD and CORQ for requested commentary whereas members of the BOC and BOS are solicited in advance for their interest and receive materials upon request. Additionally, a copy of this guideline is placed online (in a dropbox) and notices are sent to all members of the BOC and BOS instructing them on access during the Public Comment period.

If warranted and based on evidence, the guideline draft is modified in response to the public comments by the AAOS clinical practice guidelines unit and work group members. Changes that are made are summarized, and those who provide comment are informed of the revisions that result from their review. As indicated above and similar to peer review modifications, changes following the public comment period must be based on the evidence. They are detailed in a summary sheet that accompanies the document throughout the final approval process.

During the public comment period, 42 stakeholders returned the structured review form commenting on the clinical practice guideline (see Appendix X of the original guideline document).

The AAOS Guideline Approval Process

The work group submits the final guideline for approval by the Committee on Evidence-Based Quality and Value, Council on Research and Quality, and Board of Directors. These decision-making bodies are described in Appendix II of the original guideline document and are not designated to modify the contents. Their charge is to approve or reject its publication by majority vote.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Effective treatment of osteoarthritis of the knee in adults

Potential Harms

Individuals with osteoarthritis of the knee often complain of joint pain, stiffness, and difficulty with purposeful movement. The aim of treatment is to provide pain relief and improve the patient's functioning. Most interventions are associated with some potential for adverse outcomes, especially if invasive or operative. Potential harms of treatment include adverse effects of medications and complications of surgical procedures.

Contraindications

Contraindications

Contraindications vary widely by procedure. Reducing risks improves treatment efficacy and is accomplished through collaboration between patient and physician.

Qualifying Statements

Qualifying Statements

- This clinical practice guideline was developed by an American Academy of Orthopaedic Surgeons (AAOS) work group comprised of volunteer physicians and interdisciplinary clinicians as well as staff researchers with expertise in systematic reviews and statistical methods used to evaluate empirical evidence. It is an educational tool that integrates the current scientific literature and the proficiency and sound judgment that physicians typically acquire in clinical practice. The recommendations that make up this guideline are not intended to be absolute as patients vary in how they experience symptoms and respond to treatment interventions. There may be variability between patients in practice and those who participate in clinical trials. Medical care should always be based on a physician's expertise that is individually tailored to the patient's circumstances, preferences and rights.
- The work group created this guideline as an educational tool to guide qualified physicians and clinicians in making treatment decisions that improve the quality and efficacy of care. This guideline should not be construed as including all possible methods of care or excluding acceptable interventions similarly directed at obtaining favorable outcomes. The final decision to use a specific procedure must be made after assessing all concerns presented by the patient and consideration of locality-specific resources.
- This guideline is not intended for use as a benefits determination document. It does not cover allocation of resources, business and ethical considerations, and other factors needed to determine the material value of orthopaedic care.
- The summary of recommendations is not intended to stand alone. Medical care should always be based on a physician's expert judgment and the patient's circumstances, values, preferences and rights. For treatment procedures to provide benefit, mutual collaboration with shared decision-making between patient and physician/allied healthcare provider is essential.
- Some drugs or medical devices referenced or described in this clinical practice guideline may not have been cleared by the Food and Drug Administration (FDA) or may have been cleared for a specific use only. The FDA has stated that it is the responsibility of the physician to

determine the clearance status of each drug or device prescribed in clinical practice.

Implementation of the Guideline

Description of Implementation Strategy

Guideline Dissemination Plans

The primary purpose of this guideline is to provide interested readers with comprehensive documentation about the work group recommendations and the process followed to develop them. All guidelines are available at the American Academy of Orthopaedic Surgeons (AAOS) Web site .

Shorter versions of the guideline are available in other venues. Publication of a guideline is typically announced during an Academy press release, and published in articles authored by the work group in the *Journal of the American Academy of Orthopaedic Surgeons* and AAOS Now. Most guidelines are also showcased at the AAOS Annual Meeting on Academy Row and as part of the Committee Scientific Exhibits.

Selected guidelines are disseminated by webinar, website, radio, briefings and continuing education. Examples include an online module for the Orthopaedic Knowledge Online website, radio media tours, media briefings, and AAOS' continuing medical education (CME) curriculum and Resource Center.

Other dissemination efforts outside of the AAOS include submission to the National Guideline Clearinghouse and to the Guidelines International Network database, as well as distribution at the annual meetings of other medical specialty societies.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on treatment

of osteoarthritis of the knee. 2nd ed. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2013 May 18. various p. [137 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2013 May 18)

Guideline Developer(s)

American Academy of Orthopaedic Surgeons - Medical Specialty Society

Source(s) of Funding

The American Academy of Orthopaedic Surgeons funded this clinical practice guideline without any financial support from outside commercial sources.

Guideline Committee

American Academy of Orthopaedic Surgeons (AAOS) Treatment of Osteoarthritis of the Knee Guideline Work Group

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Financial Disclosures/Conflicts of Interest

In accordance with American Academy of Orthopaedic Surgeons (AAOS) policy, all individuals whose names appear as authors or contributors to this clinical practice guideline provided full disclosure of and were vetted for potential conflicts of interest prior to the introductory meeting.

Refer to Appendix XII in the original guideline document for individual work group members' conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Orthopaedic Surgeons (AAOS). Treatment of osteoarthritis of the knee (non-arthroplasty). Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2008 Dec 6. 263 p.

Guideline Availability

Electronic copies: Available from American Academy of Orthopaedic Surgeons Web site .

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (800) 626-6726 (800 346-AAOS); Fax: (847) 823-8125; Web site: www.aaos.org .

Availability of Companion Documents

The following is available:

- Treatment of osteoarthritis of the knee: evidence-based guideline, 2nd edition. Summary of recommendations. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2013. 13 p. Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Orthopaedic Surgeons Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 8, 2009. The information was verified by the guideline developer on May 4, 2009. This summary was updated by ECRI Institute on July 31, 2013. The updated information was verified by the guideline developer on August 31, 2013. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines.

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